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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,118	06/30/2000	Samantha J. Busfield	7853-211	6846

7590 12/18/2001

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EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	14

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/610,118	Busfield et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on Sep 24, 2001

2a) [ ] This action is **FINAL.** 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) 132-264 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) 132-264 is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirem

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) [X] Notice of References Cited (PTO-892)

16) [X] Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8

18) [ ] Interview Summary (PTO-413) Paper No(s). _____

19) [ ] Notice of Informal Patent Application (PTO-152)

20) [ ] Other

DETAILED ACTION

Note: The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Amy DeCloux, Group Art Unit 1644, Group 1640.

1. Applicant's election WITH traverse of Group I (Claims 59-131) encompassing single chain antibodies, Fab and antibodies produced by the hybridoma PTA-2442, and the species of SEQ ID NO:66, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

2. It is noted that in Paper No. 13, filed 9/24/01, applicant canceled claims 59-131 and added claims 132-264.

3. A) Applicant is advised that should claims 155, 156, 161, 162, 175, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 213, 214, 233, 234, 235, 236, 237, 238, 239, 240, and 241, be found allowable, claims 152, 153, 142, 146, 163, 176, 177, 178, 179, 181, 182, 183, 184, 180, 185, 148, 149, 222, 223, 224, 225, 226, 227, 228, 229, and 230, respectively will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

B) Regarding the IDS filed 1/25/01, Paper No.8, applicant states that copies of references AC-AF, AU, AY, BA, BN, BX, CA and DD-DJ are submitted with the 1449 form filed 1/25/01. However said references were not found by the instant examiner. Furthermore applicant also states that references AA-AB, AG-AT, AV-AX, AZ, BB-BM, BO-BW, BY-BZ, CB-DC and DK have not been included because said copies are available in parent application No. 09/345,068, filed 6-30-1999. However said application does not appear to be the parent of the instant application, and accordingly does not contain said references.

Therefore, the information disclosure statement filed 1/25/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

C) Claims 137, 139, 141, 143, 145, 147, 149, 151, 153, 156, 158, 160, 167, 170, 172, 174, 179, 182, 184, 186, 190, 193, 195, 197, 202, 204, 206, 209, 214, 217, 219,

221, 225, 225, 232, 236, 243, 244 and 253 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is not clear how the recitation of a sequence such as SEQ ID NO:66 which is inherent to what is encoded by deposit No. PTA-2442, further limits the base claim.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, In such full, clear, concise, and exact terms as to enable any person skilled In the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 132-264 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 132-264 are not supported by the specification or by the claims as originally filed. There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter.** Applicant is invited to point out by page and line number in the instant specification, specific, detailed support for each of the newly added 132 claims. Particularly applicant must point out where each of the recited combinations and permutations of CDRs is supported.

6. Claims 132-264 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that antibodies are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete

name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

NOTE THE CURRENT ATCC DEPOSITORY ADDRESS
American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

It is noted that the sequence of an entire immunoglobulin satisfies the biological deposit of said immunoglobulin. Note that satisfaction for the biological deposit of the specific antibody requires the disclosure and recitation of its entire amino acid sequence and not based upon partial sequences.

7. Claims 132-264 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to an antibody that specifically binds a Tango 268 antigen, minimally comprising a CDR encoded by the cDNA insert of the plasmid deposited with the ATTC as patent Number PTA-2442, wherein said antibody immunospecifically binds to a TANGO antigen. The instant specification discloses in Table 7 an antibody wherein said antibody comprises a VL CDR1, VL CDR2, VL CDR3, VH CDR1, VH CDR2, and VH CDR3 which is encoded by the VL CDR1, VL CDR2, VL CDR3, VH CDR1, VH CDR2, and VH CDR3 of the cDNA insert of the plasmid deposited with ATTC as patent deposit Number PTA-2442.

However, the instant specification provides insufficient guidance and direction that the instant antibody recited in instant claims 231-232 even binds a TANGO 268 antigen; further the antigen recognized by the said antibody can not be deduced since it is not clear from the instant disclosure exactly what immunogen from the many TANGO epitopes and TANGO proteins/peptides disclosed in the instant specification was used to generate said antibody or what screening method was used. Accordingly, it is not clear if said antibody binds human or murine TANGO 268 or both given that the instant application discloses only Tango sequences originating in mus musculus or homo

sapiens.

Therefore, in view of the insufficient guidance and direction in the instant specification regarding the antigen reactive with the antibody recited in instant claims 231-232, which details the sequence of all three CDR domains of both the heavy and light chain, it is even less clear from the instant disclosure that an antibody comprising only one defined CDR region and several undefined CDR regions as recited in the instant claims 132-230 and 233-264 is able to bind any TANGO antigen. Therefore, the specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed in claims 132-230 and 233-264 without an undue amount of experimentation. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of combinations of CDR domains that must be tested in order to enable specific binding to a Tango 268 antigen. Janeway et al (Immunobiology Fourth Edition) teaches that the association of different heavy and light chain variable regions form the antigen binding site and that the surface of the antibody molecule formed by the juxtaposition of the CDRs of the heavy and light chains creates the site to which the antigen binds, and that as the sequences of the CDRs are different in different antibodies, so are the shapes of the surfaces created by these CDRs. (see page 87, last two paragraphs). Therefore, from the teachings of Janeway and from the insufficient guidance and direction in the instant specification, it is not clear that any of the antibodies recited 132-230 and 233-264, which encompass up to five undefined CDR regions, will be able to bind a TANGO 268 epitope as recited in the instant claims and/or as disclosed as the asserted utility in the instant specification.

Claims 254 and 255 are included in this rejection since it is not clear from the instant specification how one would identify a purified antibody that competes with a scFv antibody encoded by the cDNA insert of the plasmid deposited with ATTC as a patent deposit Number PTA-2442 for binding to a TANGO 268 antigen, since said antigen that said scFv binds to is not clearly defined in the instant specification and accordingly one could not set up the experiment to screen for a competing antibody.

In view of the quantity of experimentation necessary to use the claimed invention, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

8. Claims 132-230, 233-241, 244-251 and 256-264 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to an antibody that specifically binds a Tango 268 antigen, minimally comprising a CDR encoded by the cDNA insert of the plasmid

deposited with the ATTC as patent Number PTA-2442, wherein said antibody immunospecifically binds to a TANGO antigen. The instant specification discloses in Table 7 an antibody wherein said antibody comprises a VL CDR1, VL CDR2, VL CDR3, VH CDR1, VH CDR2, and VH CDR3 which is encoded by the VL CDR1, VL CDR2, VL CDR3, VH CDR1, VH CDR2, and VH CDR3 of the cDNA insert of the plasmid deposited with ATTC as patent deposit Number PTA-2442. Said disclosure does not adequately describe the scope of the claimed genus of antibodies, each of which encompasses a substantial variety of subgenera. With the exception of the antibodies recited in claims 231-232, 242-243 and 252-255, which details the sequence of all three CDR domains of each of the heavy and light chain, the instant claims do not define all six CDRs and therefore there is no description of the required structural features of said antibodies that would confer the ability to bind a TANGO antigen. Therefore, the structure of the antigen binding site of the antibodies recited in the instant claims is not conventional in the art and one of skill in the art would not recognize from the disclosure that applicant was in possession of the genus of an antibody that specifically binds a Tango 268 antigen, minimally comprising a CDR encoded by the cDNA insert of the plasmid deposited with the ATTC as patent Number PTA-2442.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.)

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner,
December 6, 2001

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644